1. **Name, address, telephone number, contact person and date of preparation of summary.**

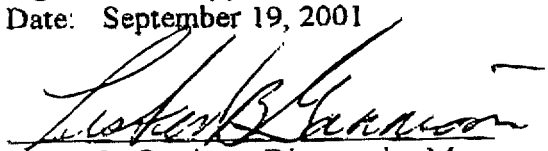
Applicants name and address

Astoria-Pacific, Inc.
FDA Establishment No. 3050015
15130 SE 82nd Drive
Post Office Box 830
Clackamas, OR 97015-0830

Tel 1-503-657-3010
Fax 1-503-655-7367

Raymond L. Pavitt, President
Official Correspondent

Signature of Applicant:
Date: September 19, 2001



Lester B. Garrison, Diagnostics Manager
Submission Correspondent

2. **Name of the device, including trade or proprietary name, and classification name.**

Product Classification

Regulation Number	21 CFR 8642.1118
510(k) Number	K010844
Classification Panel	Clinical Chemistry
Device Classification	Class II

Product Nomenclature

Common Name	Biotinidase Screening Test
Classification Name	Biotinidase Test System
Proprietary Name	Astoria-Pacific SPOTCHECK® Biotinidase Kit, 50-Hour
Model Number	Astoria-Pacific Part No. 80-8000-13K

3. Identification of the legally marketed device for which substantial equivalence is claimed.

Product Classification

Regulation Number	21 CFR 862.1118
510(k) Number	K992284
Classification Panel	Clinical Chemistry
Device Classification	Class II

Product Nomenclature

Common Name	Biotinidase Screening Test
Classification Name	Biotinidase Test System
Proprietary Name	Wallac Neonatal Biotinidase Test Kit
Model Numbers	NB-1000; NB-4000

4. Description of the Device

BIOTINIDASE 50 HOUR REAGENT KIT

API Part No. 80-8000-13K
Biotinidase Test System

Biotinidase activity is determined by measuring the color that develops from p-Aminobenzoic Acid (PABA) after PABA is released from Biotinyl-p-Aminobenzoate (Biotin-PAB). Samples with biotinidase activity develop a purple color. Samples without biotinidase activity remain straw-colored.

Samples of whole blood collected on standardized filter paper are eluted in water and then incubated with Biotin-PAB in a pH 6 buffer. After incubation, the PABA released is separated from proteins in the sample by on-line dialysis. The PABA is diazotized and coupled to a napthol derivative to form an azo dye by the successive addition of sodium nitrite, acidic ammonium sulfamate and finally. N-1-naphthylethylenediamine dihydrochloride (NED). The color is measured colorimetrically at 550 nm.

$$\text{Biotin-PAB} \xrightarrow[\text{pH 6}]{\text{Biotinidase}} \text{Biotin} + \text{PABA}$$

$$\text{PABA} \xrightarrow[\text{NED}]{NO_2,\ NH_2SO_3} \text{Purple chromophore}$$

The color developed is proportional to the biotinidase activity in the sample. A standard curve prepared from a stock PABA solution is used to quantitate the results.

5. Statement of Intended Use

This method is for the semi-quantitative determination of biotinidase, EC 3.5.1.12, activity in dried whole blood spots using the Astoria-Pacific SPOTCHECK® Analyzer. Measurement of biotinidase activity is primarily for the diagnosis and treatment of biotinidase deficiency in newborns. This method is intended for in vitro diagnostic use to aid in screening for decreased levels of biotinidase activity and not for monitoring purposes.

This device is for use by trained, qualified laboratory personnel.

6. A Summary of the Technological Characteristics of the Device

Within-Run Precision, S_{WR}

Biotinidase Activity, ERU	Deficient n = 32	Partial Activity n = 44	Normal n = 44
Average	0.54	14.6	79.6
S.D.	0.09	0.47	3.8
C. V.	17%	3.2%	4.7%

Total Precision, S_T

Average	0.54	14.6	79.6
S.D.	0.30	0.94	4.6
C. V.	56%	6.4%	5.8%

Device Comparison

The performance of the SPOTCHECK Biotinidase 50 Hour Reagent Kit and a fluorometric device were evaluated by analyzing 158 patient samples classified by the fluorometric device as normal (134); Partial (3) and biotinidase deficient (21). Nine of the twenty-one deficient samples are from persons clinically confirmed as biotinidase deficient. Samples analyzed with the API SPOTCHECK Reagent Kit were treated according to the procedures under Specimen Collection and Preparation for Analysis.

Device Comparison		Fluorometric Device		
		Normal (134)	Partial (3)	Deficient (21)
API SPOTCHECK Biotinidase Reagent Kit	ormal Above 20 ER	122 of 134	0	0
	artial -20 ERU	12 of 134	2 of 3	1 of 21
	eficient Below 6 ERU	0	1 of 3	20 of 21

INTERFERING SUBSTANCES

Sulfonamides react with the color developing reagents to give an intense purple color. Sulfamethoxazole combined with trimethaprim, sulfioxazole, and any sulfonamide with a free or hydrolyzable primary aromatic amino group may interfere in this fashion.

Phenytoin, ampicillin, gentamicyn sulfate, vitamin K, penicillin G potassium, kanamycin sulfate, adrenocorticotropic hormone, valproic acid and sodium phenobarbital do not interfere at therapeutic concentrations. Samples spiked with up to 2.5 g/dl of combined albumin and globulin showed no interference. Protein added above that level increased the response. Samples spiked with up to 100 mg/dl of hemoglobin showed no interference. Samples spiked with up to 250 mg/dl of lipids showed no interference. Lipids added above that level decreased the response.

7. Conclusion

Based on performance characteristics and comparison data, we believe this device to be safe, effective, and substantially equivalent to the legally marketed predicate device.

END 510(k) SUMMARY

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR §807.92, as revised April 1, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 21 2001

Mr. Raymond L. Pavitt
President, Official Correspondent
Astoria-Pacific, Inc.
15130 S.E. 82nd Drive
P.O. Box 830
Clackamas, OR 97015-0830

Re: k010844
Trade/Device Name: Astoria Pacific SPOTCHECK® Biotinidase Kit, 50 hour
Regulation Number: 21 CFR 862.1118
Regulation Name: Biotinidase test system
Regulatory Class: Class II
Product Code: NAK
Dated: July 26, 2001
Received: August 6, 2001

Dear Mr. Pavitt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010844
Device Name: _____

Indications For Use:

Intended Use

The Astoria-Pacific® SPOTCHECK® Biotinidase 50-Hour Reagent Kit is for the semi-quantitative determination of Biotinidase activity in whole blood dried on filter paper using the Astoria-Pacific SPOTCHECK Analyzer. Measurements of biotinidase activity are primarily for the diagnosis and treatment of Biotinidase deficiency in newborns. This device is for use by trained, qualified laboratory personnel. For In Vitro Diagnostic Use.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Alexander for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010844

Prescription Use ✓ **OR** **Over-The-Counter Use** ____
(per 21 CFR 801.109)

(Optional Format 1-2-96)